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August 20, 2004

Division of Dockets Management
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Docket No. 2004S-0233

Dear Sir/Madame:

This letter comes in response to your request for comments on the Notice published on May 24, 2004 in 69 Federal Register 29544, on "Stimulating Innovation in Medical Technologies," Docket No. 2004S-0233.

The National Electrical Manufacturers Association (NEMA) is the largest U.S. trade association representing America's electroindustry. The Diagnostic Imaging and Therapy Systems Division of NEMA represents over 90% of the market for x-ray imaging, CT, radiation therapy, magnetic resonance, nuclear medicine imaging, diagnostic ultrasound and medical imaging informatics equipment. We appreciate the opportunity to share our views with you.

NEMA would like to commend The Department of Health and Human Services (HHS) for recognizing the need for it to play a constructive and cooperative role in order to translate discoveries in the basic sciences into innovative medical products for patients. We agree that in order to accomplish this worthwhile objective it is essential that HHS and its agencies, e.g. National Institutes of Health (NIH), Food and Drug Administration (FDA), Centers for Medicare and Medicaid Services (CMS) and Centers for Disease Control and Prevention (CDC) work together in an efficient and cooperative manner. NEMA would like to open an ongoing dialogue with you to achieve this goal.

In the Federal Register Notice, HHS has sought public input on a number of important questions for stakeholders, which are, and will be, pivotal to government agencies' impacts on facilitating product development. We especially wish to focus attention on question # 4 because we strongly believe that it holds the key to addressing the other 6 questions you have raised.

Question 4 asks:

"What forums should HHS use to survey constituents about obstacles to innovation (e.g. public meetings, contract research, focus groups)?"

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We believe that HHS and its agencies can best deal with the issues posed by these questions, by opening and maintaining an ongoing dialogue with critical stakeholders. This is crucial because these issues are extremely intricate and complex and have very significant ramifications for HHS and its agencies, as well as for the medical device industry and patients.

It is critical that the approaches, policies and procedures which HHS and its agencies implement for the purpose of accelerating product development and application of new medical technologies be compatible with industry product development processes. The issues inherent in the product approval and Medicare coverage and reimbursement processes are very complicated, and must be addressed in a careful, deliberative, step-by-step way. Even with the best of intentions, failure to take the necessary time to give these matters the careful attention they deserve will result in implementation of policies and procedures that will frustrate and impede, rather than facilitate, development and application of new medical technologies.

NEMA would like to initially suggest two areas which might be fruitful for discussion for industry and HHS and its agencies:

1. Development of emerging medical imaging screening technologies

2. HHS assistance in funding and collaboration in facilitating clinical trials

These are very critical healthcare issues. Medical screening technologies have become ever more important as the nation's healthcare system increasingly focuses on prevention of disease. This has been evidenced by the growth of screening mammography, for example. The development of more sensitive and sophisticated medical screening technologies holds tremendous potential for enhancing the health and quality of life for patients. It is important to recognize that these technologies can only be brought to market if HHS and its respective regulatory agencies do not impose unnecessary, onerous regulatory burdens upon manufacturers, and if these agencies do not work at cross purposes to one another.

In a number of instances, one of the essential steps which will be needed to assess whether a medical technology innovation may be approved, and covered, for patient use involves conducting a clinical trial to evaluate its performance. Conducting a clinical trial is a time consuming and often very expensive proposition. Costs of a trial are often prohibitive for many medical device manufacturers. HHS and its respective agencies can play a critical role by assisting in the funding of clinical trials, and otherwise facilitating the processes by which designs for studies are reviewed, evaluated and approved, and in monitoring the progress of trials. The design of a clinical trial and conducting the actual study are complex processes requiring strict attention to detail. Implementation of procedures and policies for funding and conducting clinical trials should only be developed through maintaining a dialogue between HHS

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and relevant stakeholders on an ongoing basis, so that the needs and concerns of all parties can be adequately addressed.

An example of a successful partnership of HHS regulatory agencies and imaging manufacturers is The National Forum on Biomedical Imaging and Oncology (NCI Forum). Now in its 5th year, the NCI Forum has as its objective to bring together developers in academia and industry and leaders in critical government agencies involved in the funding, regulation or reimbursement of technology to facilitate adoption of new medical technology innovations in the oncology field. The Forum showcases the latest developments in medical technologies, and is a mechanism to enable product developers and regulators to forge creative solutions to help remove or reduce regulatory or reimbursement obstacles, and enhance the flow of the product development process.

The Forum has spurred the formation of creative relationships among HHS agencies and HHS agencies and stakeholders. A few examples of specific instances of these collaborations among HHS agencies include:

-*Interagency Council on Biomedical Imaging in Oncology* – This Council is composed of staff from NCI, FDA and CMS, and serves as a sounding board for investigators and manufacturers attempting to bring medical imaging technology to market.
- *CDER cross Agency working group* - The Center for Drug Evaluation and Research formed a cross agency working group for use of imaging as a biomarker in drug development.
-*Digital Mammography Clinical Trial* – This is a trial which will compare the technical capabilities of full-field digital mammography with that of screen-film mammography.

In conclusion, to address these vitally important and complex issues, NEMA, as a critical stakeholder in the development of innovative medical technologies, is ready and eager to engage HHS and its agencies in an ongoing dialogue in which these issues can be fully discussed, debated and resolved. We would like to collaborate with HHS and its agencies as partners in this process. We believe that this is the best way to remove any roadblocks which stand in the way of progress toward bringing innovative medical technologies to market.

If you have any questions, or need additional information, please feel free to contact me. I can be reached at (703) 841 – 3248 or ric _ eaton@nema.org

We look forward to hearing from you on how we can best begin our dialogue on these issues, as well as future areas, and to working together to bring the benefits of innovative medical device technologies to patients. Together we can enhance the quality of healthcare for Americans.

Sincerely,

Richard M. Eaton,
Industry Manager

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